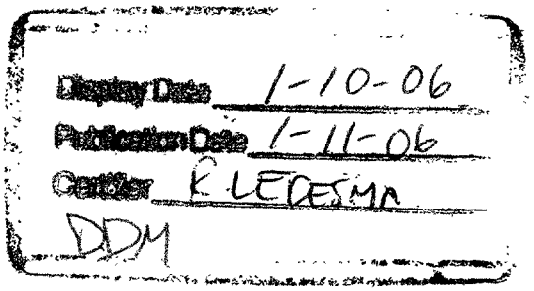
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**




**Food and Drug Administration**

**21 CFR Part 558**

# New Animal Drugs For Use in Animal Feeds; Monensin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for use of monensin Type C medicated feeds in component feeding systems (including top dress) for increased milk production efficiency in dairy cows.

**DATES:** This rule is effective [*insert date of publication in the* **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for the use of RUMENSIN 80 (monensin sodium) Type A medicated article in Type C medicated feeds fed in component feeding systems (including top dress) used for increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows. The supplemental NADA is approved as of December 15, 2005,



2006-95-735

NFR 3

and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

■ 2. Section 558.355 is amended in the last sentence in paragraph (f)(3)(xiii)(B) by removing "(d)(12)" and adding in its place "(d)(13)"; and by adding paragraph (f)(3)(xiv) to read as follows:

**§ 558.355 Monensin.**

* * * * *

(f) * * *

(3) * * *

(xiv) *Amount per ton.* Monensin, 11 to 400 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry

cows. See paragraphs (d)(2), (d)(5), (d)(6), (d)(7)(i), (d)(7)(ii), (d)(7)(iii), (d)(7)(vi), (d)(8), and (d)(13) of this section.

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Dated: January 4, 2006

January 4, 2006.

Steven D Vaughn, DVM

Steven D Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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